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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,854	07/14/2000	Keith L. Black	CEDAR-044569	4523

7590 11/19/2001

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EXAMINER

QIAN, CELINE X

ART UNIT PAPER NUMBER

1633

5

DATE MAILED: 11/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/615,854

Applicant(s)

BLACK ET AL.

Examiner

Celine Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-161 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-161 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

DETAILED ACTION

Claims 1-161 are pending in the application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, 12-24, 48-55 and 57-71, drawn to a method of delivering a medicament to an abnormal brain region and/or to a tumor by administering an activator of soluble guanylyl cyclase, classified in class 514, subclass 929.
- II. Claims 1, 11, 12-24, 48 and 56-71, drawn to a method of delivering a medicament to an abnormal brain region and/or a tumor by administering an activator of cyclic GMP-dependent protein kinase, classified in class 514, subclass 48.
- III. Claims 25-33, 35-47, 72-78 and 80-94, drawn to a method of delivering a medicament to an abnormal brain region and/or tumor through increasing permeability of capillary or arterioles by administering an activator of soluble guanylyl cyclase, classified in class 514, subclass 929.
- IV. Claims 25, 34-47, 72 and 79-94, drawn to a method of delivering a medicament to an abnormal brain region and/or tumor through increasing permeability of capillary or arterioles by administering an activator of cyclic GMP-dependent protein kinase, classified in class 514, subclass 48.
- V. Claims 95-101 and 103-114, drawn to a method of treating a malignant tumor by administering an activator of soluble guanylyl cyclase, classified in class 514, subclass 929.

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- VI. Claims 95, 102 and 103-114, drawn to a method of treating a malignant tumor by administering an activator of GMP-dependent protein kinase, classified in class 514, subclass 48.
- VII. Claims 115-121 and 123-134, drawn to a method of treating a malignant tumor through increasing potassium flux through a calcium-activated or ATP-sensitive potassium channel in an endothelial cell membrane by administering a nitric oxide donor, classified in class 514, subclass 929.
- VIII. Claims 115, 122 and 123-134, drawn to a method of treating a malignant tumor through increasing potassium flux through a calcium-activated or ATP-sensitive potassium channel in an endothelial cell membrane by administering an activator of GMP-dependent protein kinase, classified in class 514, subclass 48.

Claims 135-144 and 146-160 are generic claims to Groups I, III, V and VII, and will be examined together upon election of one of these groups. Claims 135, 145, 146-153 and 161 are generic claims to Groups II, IV, VI and VIII, and will be examined together upon election of one of these groups.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I, III, V and VII are patentably distinct from inventions of Group II, IV, VI and VIII because the inventions are drawn to methods that require different starting materials and modes of operation. The methods of Group I, III, V and VII involves administering activators of guanylyl cyclase whereas the methods of Group II, IV, VI and VIII involves administering activators of cyclic GM-dependent kinase. These are chemically distinct

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compounds and require different conditions to activate potassium channel because they activate two distinct proteins with different and distinct functions. Thus, the inventions of Group I, III, V and VII are patentably distinct from inventions of Group II, IV, VI and VIII.

Inventions I and III are patentably distinct because the inventions are drawn to methods that require different modes of operation. The method of delivering a medicament to an abnormal brain region of Group I involves different steps than the method of selectively delivering a medicament through increased potassium flux through a calcium-activated or ATP-sensitive in an endothelial cell membrane of Group II. Thus, the inventions of Group I and III are patentably distinct.

Inventions I and V are patentably distinct because the inventions are drawn to methods that require different modes of operation. The method of delivering a medicament to an abnormal brain region of Group I involves different steps than the method of treating a malignant tumor of Group V. Thus, the inventions of Group I are patentably distinct from the inventions of Group V.

Inventions I and VII are patentably distinct because the inventions are drawn to methods that require different modes of operation. The method of delivering a medicament to an abnormal brain region of Group I involves different steps than the method of treating a malignant tumor of Group V. Thus, the inventions of Group I are patentably distinct from the inventions of Group VII.

Inventions III and V are patentably distinct because the inventions are drawn to methods that require different modes of operation. The method of delivering a medicament to an abnormal brain region of Group III involves different steps than the method of treating a

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malignant tumor of Group V. Thus, the inventions of Group III are patentably distinct from the inventions of Group V.

Inventions V and VII are patentably distinct because the inventions are drawn to methods that require different modes of operation. The method of delivering a medicament to tumor of Group V involves different steps than the method of selectively delivering a medicament through increased potassium flux through a calcium-activated or ATP-sensitive in an endothelial cell membrane of Group VII. Thus, the inventions of Group V and VII are patentably distinct.

Inventions of Groups II, IV, VI and VIII are patentably distinct from each other for the same reason as given for the differences between Groups I, III, V and VII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and because the searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0823. The examiner can normally be reached on 8:30-5:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J Clark can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian
November 16, 2001



REMY YUCEL, PH.D
PRIMARY EXAMINER